

## REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance. The present amendment is being made to facilitate prosecution of the application.

### I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-10, 15-29, 42-44, 56, 57, 67-76, 81-95, 108-110, 122, 123 and 133-136 are in this application. Claims 11-14, 30-41, 45-55, 58-66, 77-80, 96-107, 111-121 and 124-132 were previously withdrawn without prejudice or disclaimer of subject matter.

Claims 133-136 are hereby added. Claims 1, 27, 42, 56, 67, 93, 108, 122, 133 and 135 are independent. Claims 1-5, 9, 10, 27, 42, 56, 67-71, 75, 76, 93, 108, 122 are hereby amended. No new matter has been introduced. Support for this amendment is provided throughout the Specification as originally filed, and, for example, in paragraphs [0009], [0018], [0042] and [0043] of the Published Application.

Changes to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §101, §102, §103, or §112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### II. REJECTIONS UNDER 35 U.S.C. §112

Claims 1-10, 15-29, 42-44, 56, 57, 67-76, 81-95, 108-110, 122, 123 and 133 have been amended to overcome the §112 rejection of these claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §112 rejection.

- Applicants note that apparatus claims 26, and 27-29 were only rejected under §112 and, therefore, should now be in condition for allowance.
- Applicants note that method claims 67-76, 81-95, 108-110, 122, 123 were only rejected under §112 and, therefore, should now be in condition for allowance.

### III. REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 1-10, 15-24, 42-44, 56, 57 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over WO 0041764 (U.S. Patent No. 6,885,896) to Minogue et al. (hereinafter, merely “Minogue”) in view of Official Notice.

Claim 25 was rejected under 35 U.S.C. §103(a) as allegedly unpatentable over WO 0041764 (U.S. Patent No. 6,885,896) to Minogue in view of Official Notice.

In view of the amendments herein, Applicants respectfully traverse this rejection.

Independent claim 1, as amended, is representative and recites, *inter alia*:

“a signal generator

...

an electrode apparatus for applying the signal

...

wherein the predetermined parameters of the electrical pulse signal are selected to cause a predetermined cardiac output of at least 50% of the maximum cardiac output of the subject;

...

a feedback mechanism that maintains the predetermined cardiac output by controlling said signal generator based upon the cardiovascular response.

As understood by the Applicants, Minogue discloses an apparatus for attaching at least three electrodes for stimulating the muscles of a subject. Minogue discloses a specified range of electrode physical sizes and electric pulse parameters that may be provided through the

electrodes. That is, Minogue discloses a device wherein the electrodes are defined by physical size and a pulse to be provided.

In contrast, the present invention recites, “predetermined parameters of the electrical pulse signal are selected to cause a predetermined cardiac output of at least 50% of the maximum cardiac output of the subject . . . and . . . a feedback mechanism that maintains the predetermined cardiac output by controlling said signal generator based upon the cardiovascular response.”

Thus, in the present invention, the parameters of the electrical pulse are determined by the cardiovascular response of the subject. Further, the feedback mechanism uses the cardiovascular response to adjust the electrical pulses to maintain the specified cardiovascular response.

The Office Action notes that the Minogue device is capable of meeting the functional requirements of the present invention. However, as amended, the present invention, (1) specifies the electrical pulse requirements in terms of the cardiovascular response, and (2) uses a feedback system to maintain a predetermined cardiovascular response. Minogue does not specify the electrical pulse requirements in terms of a cardiovascular response nor does Minogue teach maintaining the desired cardiovascular response through adjustment of the pulse.

Additionally, as argued below, Applicants contend the Office Action impermissibly relies on Official Notice to bridge the gap over feedback elements not taught by Minogue.

Thus, claim 1 is patentable over Minogue at least because that reference does not teach or suggest each and every element recited in the claim. In particular, Minogue does not teach suggest, “predetermined parameters of the electrical pulse signal are selected to cause a predetermined cardiac output of at least 50% of the maximum cardiac output of the subject . . . and . . . a feedback mechanism that maintains the predetermined cardiac output by controlling said signal generator based upon the cardiovascular response” as recited in claim 1.

For reasons similar or somewhat similar to those described above with regard to independent claim 1, independent claims 27, 42 and 56 are also believed to be patentable.

**A. NON-REJECTED APPARATUS CLAIMS**

Applicants note that apparatus claims 26 (dependent from claim 25) and claims 27-29 were not rejected under §103. The only rejection of these claims was under §112. As discussed above, claims 26 and 27-29 have been amended herein to overcome the §112 rejection and should, therefore, now be in condition for allowance.

**B. NON-REJECTED METHOD CLAIMS**

Applicants note that method claims 67-76, 81-95, 108-110, 122, 123 were not rejected under §103. The only rejection of these claims was under §112. As discussed above, claims 25-29 have been amended herein to overcome the §112 rejection and should, therefore, now be in condition for allowance.

Further, amended claim 67 is representative and recites, *inter alia*:

“selecting the predetermined parameters of the electrical pulse signal to cause a predetermined cardiac output of at least 50% of the maximum cardiac output of the subject;

...  
monitoring the cardiovascular response of the subject; and

...  
maintaining the predetermined cardiac output by controlling said signal generator based upon the cardiovascular response.” (emphasis added).

Minogue does not teach selecting the pulse parameters to effect muscle vibrations that result in a cardiac output of at least 50%. Additionally, the cardio response is maintained at the at least 50% level by adjusting the pulse parameters from the signal generator. Thus, the

electrical pulse parameters of the present invention are selected based upon a cardiac response and adjusted to maintain that response.

The method claims are not obvious in view of Minogue. Applicants contend that the methods of the present invention are patentable over Minogue for at least the reason that those claims do not specify the apparatus that is used to perform the method and Minogue does not disclose the claimed method.

Thus, claim 67 is patentable over Minogue.

For reasons similar or somewhat similar to those described above with regard to independent claim 67, independent claims 93, 108 and 122 are also believed to be patentable

**C. Applicants challenge the factual assertion as Not Properly Officially Noticed or not Properly Based Upon Common Knowledge**

From the MPEP 2144.03(E): “Any rejection based on assertions that a fact is well-known or is common knowledge in the art without documentary evidence to support the examiner’s conclusion should be judiciously applied. Furthermore, as noted by the court in *Ahlert*, any facts so noticed should be of notorious character and serve only to ‘fill in the gaps’ in an insubstantial manner which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection. *See, for example, In re Zurko*, 258 F.3d 1379, 1386; *In re Ahlert*, 424 F.2d 1088, 1092.”

Further, “[a]s noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be ‘capable of such instant and unquestionable demonstration as to defy dispute.’ (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).” MPEP 2144.03.

The Office Action asserts, without support, “It would have been obvious . . . to modify the system of Minogue, with a monitoring device for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor since it was known . . . to allow stimulation . . . within physiological limits and a safe level to the patient so the patient does not overexert himself or go outside of the physiological limits.”

Applicants contend that this is a mere conclusory statement and an impermissible reliance on Official Notice. The Applicants contend these features are not of notorious character nor insubstantial. Certainly, the monitoring and feedback features recited in claims are not capable of “instant and unquestionable demonstration as to defy dispute.”

Indeed, as amended, the claims require a specified cardiovascular response of at least 50% of the maximum cardiac output of a subject. Further, pulses are adjusted to induce muscle vibrations that maintain the cardio response in the specified range. These features are neither “basic knowledge” nor “common sense.” *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) (“Deficiencies of the cited references cannot be remedied by the Board’s general conclusions about what is ‘basic knowledge’ or ‘common sense.’”).

Applicants contend that claims 1, 27, 42 and 56 recite substantive features that can not be overcome with Official Notice.

#### IV. NEW CLAIMS 133-136

Independent claim 133 is representative and recites, *inter alia*:

“inducing muscle vibrations in a predetermined frequency range by selecting parameters of the electrical pulse signal;

...

maintaining the muscle vibrations in the predetermined frequency range to cause a cardiac output of at least 50% of the maximum cardiac output of the subject.”  
(emphasis added).

The emphasized features are neither taught nor suggested by Minogue. Minogue does not teach that muscle vibrations are maintained in a desired frequency range so that a cardiac output of at least 50% of the maximum is maintained. Applicants contend that the methods of the present invention are patentable over Minogue for at least the reason that those claims do not specify the apparatus that is used to perform the method and Minogue does not disclose the claimed method.

Thus, claim 133 is patentable over the Minogue reference.

Claim 134 depends from claim 133 and should be patentable for at least the same reasons. In addition, claim 134 adds the limitation that the frequency of the muscle vibrations is maintained in the range of 3 Hertz to 12 Hertz. This limitation provides a range that is appropriate while maintaining the desired cardiac output. Minogue does not disclose the frequency range appropriately maintained to achieve the predetermined cardio output of at least 50% of the maximum cardio output of the subject.

For reasons similar or somewhat similar to those described above with regard to claims 133 and 134, claims 135 and 136 are also believed to be patentable

## V. DEPENDENT CLAIMS

The other claims are dependent from one of the claims discussed above and are therefore believed patentable for at least the same reasons. Because each dependent claim is also deemed to define an additional aspect of the invention, however, the individual reconsideration of the patentability of each on its own merits is respectfully requested.

CONCLUSION

Claims 1-10, 15-29, 42-44, 56, 57, 67-76, 81-95, 108-110, 122, 123 and 133-136 are in condition for allowance. In the event the Examiner disagrees with any of statements appearing above with respect to the disclosure in the cited reference, or references, it is respectfully requested that the Examiner specifically indicate those portions of the reference, or references, providing the basis for a contrary view.

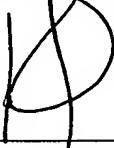
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In view of the foregoing amendments and remarks, it is believed that all of the claims in this application are patentable and Applicants respectfully request early passage to issue of the present application.

Respectfully submitted,

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